



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

E-MAILED

February 6, 2019

OPP Decision Number: 538753

Simone Seifert-Higgins, Ph.D.
Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW
Washington, DC 20005

Subject: Application Deficiency
Product Name: M1768 Herbicide
EPA Registration Number: 524-617
Application Date: January 22, 2018
EPA Receipt Date: January 25, 2018

Dear Dr. Seifert-Higgins:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105. Please ensure that you consider each of the options below in determining how and when you respond to this letter.

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiency identified in the Agency's review at this time is:

1. A field volatility study conducted using Xtendimax on dicamba-tolerant corn is required to complete the review of this request. In order to ensure that the data collected is what is needed to complete a review, we strongly encourage the submission of a protocol before initiating this study.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please respond to this letter within 75 days of the stamped date by contacting Emily Schmid by telephone on 703-347-0189 or by e-mail at schmid.emily@epa.gov or Sarah Meadows by telephone on 703-347-0505 or by e-mail at meadows.sarah@epa.gov during the hours of 9:00 am to 3:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Emily Schmid".

Emily Schmid, Acting Product Manager 25
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Date: November 20, 2018
DP Barcode: 447230
PC code: 128931

MEMORANDUM

SUBJECT: Dicamba DGA – 90-day Screen for Proposed New Use on Dicamba-tolerant
GMO Corn (EPA Reg. No. 524-617)

FROM: Chuck Peck, Senior Environmental Fate Scientist *Chuck Peck* 2018.11.20 08:03:10 -05'00'
Michael Wagman, Biologist **MICHAEL**
Environmental Risk Branch 6 **WAGMAN** Digitally signed by
Environmental Fate & Effects Division MICHAEL WAGMAN
Date: 2018.11.20 07:16:47 -05'00'

THRU: Mark Corbin, Branch Chief *Mark Corbin* Digitally signed by Mark Corbin
William P. Eckel, Senior Science Advisor Date: 2018.11.27 11:57:43 -05'00'
Monica Wait, RAPL *William P. Eckel* Digitally signed by William P. Eckel
Environmental Risk Branch 6 Date: 2018.11.26 11:06:42 -05'00'
Environmental Fate & Effects Division

TO: Emily Schmid, Risk Manager Reviewer *Monica Wait* Digitally signed
Reuben Baris, Product Manager Team 25 by MONICA WAIT
Daniel Kenny, Branch Chief Date: 2018.11.20
Herbicide Branch 10:01:53 -05'00'
Registration Division

This memorandum transmits the Environmental Fate and Effects Division's (EFED) 90-day screen for the proposed new use of dicamba DGA salt on dicamba-tolerant GMO corn (EPA Reg. No. 524-617, XtendiMax With VaporGrip Technology).

Dicamba DGA salt is currently registered for use on conventional corn with both pre-emergence and post-emergence application timing, but the proposed new use is to add herbicide resistant corn to the product label. In addition, the following changes to corn application rates are proposed with this package:

- Increase annual use rate from 0.75 lb a.e./acre to 2.0 lb a.e./acre
- Increase pre-plant, at-planting, pre-emergence rate from 0.5 lb a.e./acre to 1.0 lb a.e./acre
- Early post-emergence (from emergence to 8 inches or V5 growth stage) remains 0.5 a.e./acre

- Late post-emergence (up to 36 inches or V8 growth stage) from 0.25 lb a.e./acre to 0.5 lb a.e./acre
- Seeking to add two states – Montana and Wyoming

40 CFR 158.1300 conditionally requires the conduct of field volatility studies for end-use products being applied in a terrestrial environment. Further, OCSPP Guideline 835.8100 specifies that the conduct of these studies be done “in areas considered representative of major areas where the pesticide is intended to be used” and “should be applied to a site which is typical of one of the sites to which the product would be applied.” To date, the submission of field volatility studies for Xtendimax have focused on pre-emergent applications to bare soil and post-emergent applications to cotton grown to 11 inches. Recent incidents regarding soybean damage have prompted the conduct of volatility studies in 2018, primarily on soybean fields. No information has been submitted on the volatility of dicamba during an application of the Xtendimax product on post-emergent corn grown to a 36-inch height. Lastly, proposed post-emergent application rates are increasing from 0.25 lbs ac/A to 0.5 lbs ac/A during the late post-emergent stage.

Given the increase in application rate, when compared to current label specifications, the different crop canopy from which dicamba may volatilize (corn versus cotton), and the recent incidents to soybean, EFED recommends that a new field volatility study be conducted using Xtendimax on dicamba-tolerant corn to ascertain if the volatilization of dicamba from the corn crop at these increased application rates is similar to volatilization observed in cotton and soybean. This will reduce uncertainty and provide information for determining the necessity and/or extent of in-field buffers meant to keep dicamba residues on the treated field.

EFED recommends the following be considered when conducting the corn volatilization study:

1. Multiple sites representing corn should be selected, to provide sufficient representation of the areas where dicamba can be applied to corn.
2. More than one postemergence growth stage should be evaluated, including 30 inch tall corn. A volatility study simulating pre-emergence conditions would not be useful, since sensitive crops are generally not present at that time.
3. A range of temperature and humidity conditions representing late spring through summer should be represented.
4. Field sizes should represent a large corn field (Farm Services Agency data suggests the average corn field is 14 acres and the 90th percentile corn field is 73 acres).
5. In order to estimate flux from a field when a canopy is present, an appropriate method (e.g., aerodynamic method, eddy covariance method, etc.) should be employed. Methods suitable for bare soil or minimal canopy (i.e., the integrated horizontal technique) should not be used.